

Guidelines for respiratory motion management in radiation therapy

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(Received 21 September 2012; accepted 21 November 2012)

Respiratory motion management (RMM) systems in external and stereotactic radiotherapies have been developed in the past two decades. Japanese medical service fee regulations introduced reimbursement for RMM from April 2012. Based on thorough discussions among the four academic societies concerned, these Guidelines have been developed to enable staff (radiation oncologists, radiological technologists, medical physicists, radiotherapy quality managers, radiation oncology nurses, and others) to apply RMM to radiation therapy for tumors subject to respiratory motion, safely and appropriately.

Keywords: radiotherapy; guideline; respiratory motion; respiratory motion management

INTRODUCTION

External radiotherapy synchronized with the respiration-gating signal was developed three decades ago [1]. Since then, respiratory motion management (RMM) systems in external and stereotactic radiotherapies have been investigated and improved [2, 3]. In Japan, changes to medical service fee regulations in April 2012 introduced fees for RMM in external and stereotactic radiotherapies. These techniques have been accepted as effective radiation

therapies for tumors that are subject to respiratory motion, as techniques that allow precise targeting of the tumors with prescribed radiation dosages, while reducing the dosage of irradiation to unaffected tissue surrounding tumors.

Using RMM makes it possible to reduce the irradiated area and lower the incidence of adverse effects in principle. However, it is necessary to bear in mind that, without great care, this kind of treatment poses risks that may lead to unintended treatment results.

Based on extensive discussions among the four academic societies concerned (the Japan Conformal External Beam Radiotherapy Group, the Japanese Society for Therapeutic Radiology and Oncology, the Japan Society of Medical Physics, and the Japanese Society of Radiological Technology), these Guidelines have been developed to enable staff (radiation oncologists, radiological technologists, medical physicists, radiotherapy quality managers, radiation oncology nurses, and others) involved in this kind of treatment to apply RMM to radiation therapy for tumors subject to respiratory motion, safely and appropriately.

Definitions of RMMs

RMMs

RMMs must meet the following requirements:

- (i) The treatment detailed here may only be applied when the length of respiratory tumor motion exceeds 10 mm without RMM being implemented. When the three-dimensional length of motion exceeds 10 mm, the evaluation must be that 'the length of respiratory-induced motion exceeds 10 mm'. For example, if the lengths of motion in the craniocaudal, right-left, and dorso-ventral directions are 9 mm, 4 mm, and 4 mm, respectively, the three-dimensional length is calculated as $\sqrt{9^2 + 4^2 + 4^2} = 10.6$ mm, so fulfilling the requirements of these Guidelines. The length of the respiratory-induced tumor motion must be measured under free, unforced breathing, and irregularities in the respiration due to hiccups, coughs, sneezes and deep respiration are to be excluded. Some institutions stipulate in the medical fee regulatory standards that treatment of 'tumors whose length of respiratory motion is 10 mm or longer' must be categorized as Tokkei-Shinryo (therapies covered by special schedules). However, the Guidelines detailed here assume that RMM is applicable to tumors where the length of respiratory motion exceeds 10 mm.
- (ii) In the treatment plans, it must be ascertained and recorded that the expansion of area of irradiation required to compensate for respiratory motion can be reduced to ≤ 5 mm in any direction, three-dimensionally. In regulations for medical treatment fees and institutional standards, two different expressions are used: 'expansion of field of irradiation required due to respiratory motion', and 'expansion of area of irradiation required to compensate for respiratory motion'. However, the present guidelines use only the expression: 'expansion of area of irradiation required to

compensate for respiratory motion'. 'Expansion of area of irradiation required to compensate for respiratory motion' applies to both the length of the respiration-induced tumor motion, as well as to the uncertainties related to RMM, and is equivalent to a part of the internal margin defined in ICRU (International Commission on Radiation Units and Measurements) Report 62 [4]. The three-dimensional direction refers to six directions: the cranio, caudal, right, left, dorso, and ventral directions, and the expansion of the irradiated area necessary in each direction must be 5 mm or less. If the expansion of area of irradiation required in order to compensate for respiratory motion is 5 mm or less in any one direction, then, where the irradiated area does not contract when compared with areas where RMM is not performed, it cannot be regarded as effective RMM.

- (iii) At every instance of irradiation treatment, it is necessary to ascertain and record that the tumor is included in the irradiated area determined in (ii), immediately prior to and during the irradiation. 'Immediately prior to the irradiation' refers to the time from placing the patient on the treatment table in the room where the irradiation will take place until the start of the first beam of irradiation of the treatment. 'During the irradiation' refers to the time during which each treatment beam takes place. 'A tumor is included in the irradiated area' means that a tumor is included in the planning target volume (PTV), three-dimensionally. However, 2D confirmation is acceptable during the irradiation.

When it is difficult to directly verify that the tumor is included in the irradiated area, it is acceptable to confirm this based on a marker in the body that represents the tumor positions, such as a marker in the vicinity of the tumor. In such cases, it is assumed that the method of predicting tumor positions based on the particular marker has been verified.

It is necessary to verify that a tumor is included in the irradiated area immediately prior to the irradiation. Furthermore, it is recommended to verify this state, the inclusion of the tumor in the irradiated area, during the irradiation. (According to the description in the document for medical treatment fees, this verification should be performed immediately prior to the irradiation OR during the irradiation; however, these Guidelines specify the performance of the verification immediately prior to the irradiation as indispensable.)

Real-time tumor-tracking irradiation techniques

A real-time tumor-tracking irradiation technique is an RMM technique corresponding to either (i) or (ii) below, performed under unforced breathing, and is defined as a technique that meets the requirements for RMMs specified in **RMMs**. It is acceptable to control respiration (e.g. improvement of the regularity of respiration, and shortening of the length of the respiratory tumor motion), aiming to improve the tracking accuracy and irradiation efficiency if necessary.

- (i) *A technique to perform the irradiation by analyzing the relationship between respiratory movement and tumor, and changing the irradiated field in accordance with the respiratory movement.* When a model which predicts the 3D position of a tumor with external breathing signals or other indicators is used, the model for the prediction must be created directly before the start of irradiation and updated during the treatment as required. It is necessary to measure external breathing signals or other indicators several times per second, and to verify that a tumor is included in the irradiated area based on the model of the prediction. If no prediction model is used, tumor positions must be verified three-dimensionally several times per second during the irradiation.
- (ii) *A technique to perform the irradiation onto a target while it passes through a specified position, by observing a tumor or a marker in the vicinity of the tumor using a fluoroscope during the irradiation.* When using a fluoroscope during the irradiation, it is necessary to verify that a tumor is included in the irradiated area while determining the tumor position three-dimensionally several times per second.

Examples of measures that may be considered with RMM

The following six methods are described as examples of measures to include with RMMs in the 2008 Guidelines for Radiotherapy Planning [5]:

- (i) inhalation of oxygen;
- (ii) abdominal compression: a method to secure a part of the abdomen by a band or shell, a method that uses an abdominal compression board, and others;
- (iii) learning of regular respiratory patterns (the metronome method);
- (iv) breath hold technique: active breathing control, self-respiratory cessation in deep inspiration,

self-respiratory breath-monitoring measured at two thoraco-abdominal points;

- (v) gating with respiration;
- (vi) real-time tumor-tracking: pursuing irradiation and intercepting irradiation.

If a technique satisfies the requirements listed in the definition of RMMs, it may be accepted for inclusion as an RMM. However, it is generally difficult to meet the requirements if (i) inhalation of oxygen, or (iii) learning of regular respiratory patterns, is used alone.

Measure (vi) is regarded as a ‘real-time tumor-tracking irradiation technique’, and techniques to pursue and intercept correspond to **Real-time tumor-tracking irradiation techniques** (i) and (ii), respectively.

Examples of methods to establish and verify the length of respiratory-induced tumor motion

- X-ray fluoroscopy
- 4D computed tomography (CT)
- Ultrasonography
- Cine magnetic resonance imaging (MRI)

Examples of methods to verify that a tumor is included in the irradiated area

Immediately prior to the irradiation:

- CT integrated with the therapeutic apparatus (cone-beam CT, MVCT, and others)
- CT which is installed in the room where radiotherapy is performed
- Fluoroscopy that verifies at least two directions

During the irradiation:

- Cine electronic portal imaging device (EPID)
- X-ray fluoroscopy
- Model which predicts the 3D position of a tumor from external breathing signals and others

If satisfying the requirements listed in **RMMs** and **Real-time tumor-tracking irradiation techniques**, other methods that are not specifically listed above may be utilized in RMM.

Diseases where the treatments described here may be applied

The treatments described here may be considered for the diseases listed below, but only when the length of the targeted respiratory tumor motion exceeds 10 mm.

External irradiation other than stereotactic radiotherapies:

- lung cancer, esophageal cancer, gastric cancer, liver cancer, carcinomas of the biliary tract, pancreatic cancer, renal cancer, or adrenal cancer.

Stereotactic radiotherapies:

- primary lung cancer and primary hepatic cancer which show no metastatic lesions and where the primary focus is 5 cm or less in diameter;
- metastatic lung cancer or metastatic hepatic cancer with ≤ 3 focuses, which are 5 cm or less in diameter, and with no focuses in other organs.

Note that although arteriovenous malformation of the spinal cord is treated with stereotactic radiotherapies, it has no respiratory motion and RMM considerations do not apply.

INSTITUTIONAL STANDARDS RELATED TO THE IMPLEMENTATION OF RMMS

For RMM to be adopted, it must meet the following institutional standards.

The institutional standards relate to the requirements for personnel, instruments, and the keeping of records as detailed below.

Requirements for personnel

The following staff must be available when performing the external radiotherapy involved in RMM:

- one or more full-time radiation oncologists;
- one or more full-time radiological technologists (with more than five years' experience with radiotherapy required);
- one or more medical physicists, radiotherapy quality managers or radiological technologists in charge of QA/QC.

Adoption of stereotactic radiotherapies as an RMM (other than real-time tumor-tracking irradiation) technique has the same staff requirements as external radiotherapy.

The following staff must be available when performing stereotactic radiotherapy (with real-time tumor-tracking irradiation technique) in RMM:

- two or more full-time radiation oncologists (one must have more than five years' experience with radiotherapy);
- one or more full-time radiological technologists (with more than five years' experience with radiotherapy);

- one or more medical physicists, radiotherapy quality managers or radiological technologists in charge of QA/QC.

In the Guidelines for improving collaboration among central medical facilities for cancer treatments (Document number 0301001, announced on March 1 2008, and partially revised on March 29 2011, by the Director of Health Service Bureau, Ministry of Health, Labour and Welfare), the terms, 'exclusively in charge of' and 'exclusively engaged in', are defined as follows:

'Exclusively in charge of' means that the person is exclusively in charge of the said therapy. In this case, if the person is exclusively in charge of the therapy, this person may also be in charge of other duties. However, the person must be in charge of the said therapy for more than 50% of the working hours.

'Exclusively engaged in' means that the person is exclusively engaged in the said therapy on the day when the said therapy is performed. In this case, the person must be engaged in the said therapy for more than 80% of the working hours.

Staff allocation scheme recommended for RMM

The present guidelines recommend the establishment of the following staff allocation scheme to ensure safety in the implementation of RMM. Note that the personnel in charge should not be assigned additional duties.

Radiation oncologists

It is recommended that radiation oncologists must be exclusively engaged in the therapy and not in charge of the overall treatment. It is also recommended that the radiation oncologists have more than five years' experience with radiotherapy, and be Board-certified radiation oncologists, certified medical specialists of radiotherapy, acknowledged by both the Japanese Society for Therapeutic Radiology and Oncology, and the Japan Radiological Society.

Radiological technologists

Radiological technologists must have more than five years' experience with radiotherapy, and it is recommended that they be qualified radiological technologists certified by The Japan Professional Accreditation Board for Radiotherapy Technologists. It is also recommended that radiological technologists be exclusively engaged in the therapy and not exclusively in charge of the overall treatment.

Medical physicists, radiotherapy quality managers or radiological technologists in charge of QA/QC

For the safety control of medical instruments, it is recommended that one (or more) full-time radiological technologist(s) and/or radiotherapy quality manager(s), and one or more full-time medical physicist(s) exclusively in charge of

the quality control of the radiotherapy instruments be assigned to the staff for RMM, and as well there must be a radiological technologist directly engaged in the irradiation operation, together with a physicist.

The former must be (a) qualified radiological technologist (s) specializing in radiotherapy and certified by The Japan Professional Accreditation Board for Radiotherapy Technologists, or (a) qualified radiotherapy quality manager (s) certified by the Japanese Organization of Radiotherapy Quality Management. The medical physicist(s) described here must be a medical physicist(s) certified by the Japanese Board of Medical Physics (JBMP). It is recommended that the two kinds of professionals described here must be exclusively engaged in radiotherapy and not in charge of the overall treatment. Further, they must have more than five years' experience in quality control of radiotherapy instruments, verification of irradiation plans, supplemental work related to irradiation plans, and other matters.

Radiation oncology nurses

It is necessary to ensure patient understanding and cooperation in RMM before it is implemented, and it is indispensable for medical staff to fully understand the respiratory condition while patients are receiving treatment. Although 'nurses' is a professional category that is not clearly specified in the document for medical treatment fees, these Guidelines recommend that nurses be assigned to the roles detailed here. These nurses should be exclusively in charge of the radiotherapy as it is essential to closely observe patient conditions from the time the treatment plans are established throughout the treatment.

Requirements for instruments for the treatment

Instruments meeting the following requirements must be installed in the room where the radiotherapy is performed:

- (i) instruments to accommodate respiratory motion when the length of respiratory tumor motion exceeds 10 mm, and to compensate for the expansion of irradiated areas smaller than 5 mm;
- (ii) instruments to verify and record that the tumor is included in the irradiated area immediately prior to and during the irradiation in each irradiation event.

Although not specified in the section detailing institutional standards, it is also necessary to provide instruments that can verify lengths of respiratory motion exceeding 10 mm when RMM is not performed. Such instruments are not necessarily installed in the room where the radiotherapy is performed.

Requirements for keeping records

Medical institutions authorized to treat patients with health insurance coverage must keep and store records related to

RMM, and also records related to quality control of activities. These records must be available to the public.

Records of activities

The following particulars must be verified and recorded in medical and irradiation records, as the data contained here may show therapeutic gains or adverse events.

Considerations when making treatment plans:

- (i) cases where the length of respiratory motion exceeds 10 mm without RMM. (Recording of numerical data for each of the three-dimensional directions is recommended.)
- (ii) cases where the expansion of the irradiated area has been reduced to 5 mm or less in each of the three-dimensional directions.
Immediately prior to and during the irradiation:
- (iii) cases where a tumor is included in the irradiated area based on verification imaging or a prediction model.

Quality control records

A quality control program for RMM must be developed and adhered to as a regular procedure. It is recommended that staff exclusively in charge of quality control report the results to other professionals concerned, and maintain the data in a manner to enable access as necessary. It is also recommended that the quality control program include the following data as related to the RMM procedures used in the particular institution:

- (i) data related to quality control of CT for treatment plans when using a respiratory monitoring system;
- (ii) data related to calibration and accuracy of the position of tumors (or marker in the body which represents tumor positions), or external breathing signals identified by the treatment system, including a respiratory monitoring system;
- (iii) data related to output characteristics of treatment beams and the period of time from sensing the respiratory phase to the actual irradiation when using a respiratory monitoring system;
- (iv) data related to dose verification in the RMM;
- (v) data related to radiation exposure required for the RMM;
- (vi) data related to the quality control of devices verifying the position of irradiation;
- (vii) data related to interlocking with the full treatment system, including the respiratory monitoring system.

Note that using a moving phantom that can reproduce respiratory movement is recommended for quality control of the RMM.

Treatment plans for RMM

When performing RMM, a treatment plan must be established assuming the following uncertainties:

- (i) changes in the tumor form due to respiration;
- (ii) errors between the predicted and actual tumor positions;
- (iii) the length of time from sensing the respiratory phase to the actual initiation of irradiation.

In general, the area to be irradiated is determined by adding a margin (about 5 mm) to the PTV. However, this should not be done for compensating the respiratory motion because it is for ensuring the dose at the PTV periphery.

Functions of specialists participating in RMMS

The functions of the specialists applying RMM, detailed in these Guidelines, are as follows:

Radiation oncologists

The functions of the radiation oncologists are:

- (i) to determine if RMM is appropriate for a patient;
- (ii) to explain the benefits and risks of RMM to the patient, and obtain consent to conduct the treatment;
- (iii) to conduct discussions among the specialists involved, and determine specifics of how RMM is to be conducted;
- (iv) to provide patient information required for performing RMM to other specialists involved, prior to carrying out the treatment planning (including CT scan for treatment plans);
- (v) to establish appropriate guidelines for 'the expansion of area of irradiation required to compensate for respiratory motion', based on the clinical data, particulars of the equipment characteristics in the particular institution, and patient conditions;
- (vi) to verify the records that a tumor has been included in the irradiated area immediately prior to and during the irradiation procedures. If the tumor is not included, discuss this with other specialists and determine whether it is appropriate to modify the treatment plans or to change the irradiation technique to a usual method without respiratory motion management.
- (vii) to supervise RMM to ensure that it is carried out appropriately;

- (viii) to make clinical evaluations of the appropriateness of the radiation exposure when radiation exposure cannot be avoided in carrying out RMM; and
- (ix) to discuss quality control related to RMM with the specialists involved and verify the results.

Radiological technologists

The functions of the radiological technologists are:

- (i) to perform a CT scan, considering the fluoroscopy and respiratory-induced motion, in order to verify and record the length of respiratory-induced tumor motion. Perform a CT scan for the treatment plan that takes account of RMM to be employed. As necessary, train the patient in breathing and other particulars in advance of conducting the treatment.
- (ii) to ensure a thorough understanding of the use of the instruments and devices to fix the patient position described in the *Requirements for instruments for the treatment* above;
- (iii) to ensure availability of information necessary to verify that the tumor is included in the irradiated area immediately prior to and during the irradiation, and record the results;
- (iv) to suspend irradiation if the tumor is not included in the irradiated area during the irradiation. Promptly report this to the other personnel and specialists involved, discuss this with the other specialists, and determine whether it is appropriate to modify the treatment plans or to change the irradiation technique to a usual method without RMM.
- (v) to monitor the patient during the irradiation, and be ready to stop the irradiation if required;
- (vi) in case of problems with the instruments described in the *Requirements for instruments for the treatment*, report this to the staff in charge of quality control. Work, together with the other staff, to restore the functioning of the instruments, and ensure safety.

Medical physicists, radiotherapy quality managers or radiological technologists in charge of QA/QC

The functions of the medical physicists, radiotherapy quality managers or radiological technologists in charge of QA/QC are:

- (i) to draw up and carry out a quality control plan related to RMM; also, to evaluate the results

- and be in charge of the recordings and records of the operation.
- (ii) in case of problems with the instruments described in the *Requirements for instruments for the treatment*, take the initiative to restore the functioning of the instruments and confirm safety;
 - (iii) to suggest optimal methods of carrying out RMM by taking account of the physical characteristics of the treatment beams and the total treatment time;
 - (iv) to determine whether the irradiated area has become smaller than without RMM;
 - (v) to verify that the setting of the margins and irradiated area are appropriate for the employed RMM. When determined inappropriate, develop alternative treatment plans together with the radiation oncologists involved.
 - (vi) to observe the confirmation of the position to be irradiated immediately prior to and during the irradiation, and to discuss the results with the other staff involved; to make proposals for necessary changes in the treatment plans or using the regular planned irradiation if the tumor is not included in the irradiated area.
 - (vii) in the case of radiation exposure to areas other than that planned for the treatment beams in carrying out RMM, to measure radiation exposure and report it to the other staff and specialists involved.

Radiation oncology nurses

The functions of the radiation oncology nurses are:

- (i) to conduct patient orientation prior to the treatment so that the patient will know what the treatment is going to be like, and thus to assist patient understanding of RMM;
- (ii) to consider ways to provide interventions to the patient, while regularly assessing the patient understanding of the treatment and the ability of the patient for self-care;
- (iii) in the case that a patient experiences acute pain, have in place appropriate arrangements for preventive internal analgesic medications and the timing of their administration;
- (iv) for patients who are subject to stress-induced rapid breathing, carefully consider the method of movement of the patients to the treatment room, and provide necessary assistance to ensure that the patient is comfortable during the treatment;
- (v) for patients prone to high levels of unease and stress, attend to the patient and create an

atmosphere enabling the patients to relax and be encouraged;

- (vi) for patients who may pose risks of deterioration in respiration due to having to remain in an unchanging position for a long period of time, monitor oxygen saturation.

CONCLUSIONS

These Guidelines have been developed as a general introduction aiming at providing safe and appropriate RMM. New techniques for RMM are being developed and these Guidelines may be revised as necessary. Therefore, it is necessary to pay close attention to published reports in Japan and other countries to endeavor to provide optimally appropriate RMM.

ACKNOWLEDGEMENTS

These Guidelines have been made by the Working Group of the Guidelines for respiratory motion management, consisting of members nominated from four academic societies for radiotherapy in Japan: the Japan Conformal External Beam Radiotherapy Group, the Japanese Society for Therapeutic Radiology and Oncology, the Japan Society of Medical Physics, and the Japanese Society of Radiological Technology. These Guidelines have been officially accepted by these four societies.

The draft of these Guidelines was peer-reviewed by third parties, which consisted of the Quality Assurance Committee, the Guideline Committee, the Health Insurance Committee in Japanese Society for Therapeutic Radiology and Oncology, the Quality Assurance/Quality Control Committee of the Japan Society of Medical Physics, and the Subcommittee for Radiotherapy in the Japanese Society of Radiological Technology.

We would like to express our appreciation to Kazushige Hayakawa, Masao Hoshina and Akihiro Haga for their fruitful suggestions.

CONFLICT OF INTEREST

Based on the Japanese Society for Therapeutic Radiology and Oncology Guidelines related to conflicts of interest there are the following conflicts of interest: board members of organizations, adviser: none; stock ownership: none; royalties on patents: none; lecture fees: none; manuscript fees: none; research funding: H.S., Hitachi Ltd., Mitsubishi Heavy Industries, Ltd.; M.H., Mitsubishi Heavy Industries, Ltd.; other payments: none.

FUNDING

These Guidelines were developed without receiving financial aid from other organizations. English translation has been financially supported by the research fund from the Japan Conformal External Beam Radiotherapy Group and the grant-in-aid from international standardization of four-dimensional radiotherapy, research and development program of international standard, METI 2011-2013.

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